UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287

45733 7590 06/23/2009

LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,009	GOLDMAN ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,9,11-15,23 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,9,11-15,23 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 15 September 2008 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/089,009 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 15 July 2008 is acknowledged and entered. Following the amendment, claim 9 is amended.

Currently, claims 1, 3, 5, 9, 11-15, 23 and 26-29 are pending and under consideration.

Withdrawal of Objections and Rejections:

The prior art rejection of claims 1, 3, 5, 9, 11-15, 23 and 26-29 under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160) is withdrawn in view of applicant's argument, and for the following reasons:

On page 10 of the response, applicants argue that Exhibit 1 of the March 2006 Waldmann Declaration shows that the polypeptide precipitated from MT-1 cells using anti-ILRAP antibody 5F7 (lane 2) migrates below the 37 kDa polypeptide precipitated using anti-Tac (lane 3); that Colamonici specifically reports that the relevant 37 and 20 kDa polypeptides cited by the Examiner were precipitated from MT-1 cells using anti-Tac (page 159, second column, second paragraph); and that since the analysis of Exhibit 1 to the March 2006 Waldmann Declaration was done in the same SDS-PAGE gel, the observed difference in migration cannot be attributed to variations in gel concentrations and running time, accordingly, the March 2006 Waldmann Declaration establishes that there is a size difference between the claimed polypeptide and that disclosed in Colamonici. This argument is persuasive, and above mentioned the rejection is, therefore, withdrawn.

Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the previous Office Actions mailed on 6/16/06, 11/1/06, 8/23/07, and 4/15/08.

Applicants argument filed on 15 July 2008 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 5-6 of the response, the applicant argues, with the similar argument as that in the previous response, that the Office incorrectly states that Applicants have indicated that anti-Tac did co-IP the claimed ILRAPs, and it just did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE, indicating the association of the claimed ILRAPs with IL-2R; and that Applicants have consistently argued the opposite, and Applicants actual data showing that using anti-Tac to pull down IL-2R, does not pull down enough (if any) of the claimed ILRAP so as to be identifiable by SDS-PAGE (the March 2006 Waldmann Declaration, Exhibit 3). This argument is not persuasive because if applicants statement "does not pull down enough … so as to be identifiable by SDS-PAGE" does not indicate that the antibody does pull down ILRAP, but just not enough to be detected, then it is unclear what it means, and what applicants argument really is. Does applicants statement indicates that anti-Tac does not pull down the claimed ILRAP?

At pages 6-7 of the response, the applicant argues that there is no reason for assuming, as a general principle, that a monoclonal antibody (such as anti-Tac) must co-IP every protein associated with the antigen, such that every associated protein can be visualized by SDS-PAGE, for example, if antibody binding displaces or prevents binding by an associated protein, there would be nothing surprising about the inability of the antibody to co-IP the associated protein; that the Office has provided no basis for contradicting Applicants' actual data, which show that using anti-Tac to pull down IL-2R, does not pull down (or does not pull down enough of) the claimed ILRAP so as to be identifiable by SDS-PAGE; and that alternatively or relatedly, the

claimed ILRAPs may be displaced by anti-Tac during IP. This argument is not persuasive because the Office has not contradicted Applicants' data, it is applicants who present the data, yet cannot come up with any clear conclusion as to whether the data show that the claimed ILRAP is or is not associated with IL-2R. While it is possible that that a monoclonal antibody may not co-IP every protein associated with the antigen, it does not help the issue in question: is or isn't ILRAP associated with IL-2R. This is critical because such association is being claimed, and no specific structural limitation/feature is known or provided for the claimed molecule. The burden is on applicants to provide evidence to show such. Regardless the Office's interpretation of applicants confusing argument, and applicants explanation that the ILRAPs may be displaced by anti-Tac during IP, one thing is clear, that is applicants have not provided any evidence that clear shows that the ILRAP is associated with IL-2R as claimed.

At pages 7-8 of the response, the applicant argues that the Specification reports that when Applicants pre-cleared cell lysates with anti-Tac conjugated beads, the 55 kDa band that co-immunoprecipitated with the claimed ILRAPs in Fig. 4 was reduced and was no longer visible, accordingly, there is direct evidence in Applicants' specification that some, if not all, of the 55 kDa can be depleted using anti-Tac. This argument is not persuasive because anti-Tac is for IL-2Rα (the 55 kDa band), and the pre-cleared step with anti-Tac is supposed/expected to reduce or clear the 55 kDa band molecule. Therefore, it is not an indication or evidence showing the association of the claimed ILRAPs to IL-2R. Applicants further argue that Examples 5 and 6 in the specification provides uncontradicted evidence that ILRAP interacts with IL-2R. This argument is not persuasive because Example 5 merely "suggests", and there is no show of ILRAP association with IL-2Rα (as argued by applicants, see page 8, lines 3-5, for example). Further, in Example 6, there is a "cross board reduction" of the 55 kDa band, therefore, it is possible that such is a non-specific band/reaction.

At pages 7-8 of the response, the applicant argues that the Office contends that Applicants are arguing two mutually exclusive positions, which is based, at least in part, on the Office's view that Applicants have argued that anti-Tac did co-IP the claimed ILRAPs to be visualized under co-IP conditions described by applicants; that however, Applicants have clearly and consistently argued, based on experimental evidence, that anti-Tac does not co-IP (or does

not co-IP enough of) the claimed ILRAPs under the conditions described by Applicants, such that the claimed ILRAP are not visualized by SDS-PAGE analysis of IP with anti-Tac. This argument is not persuasive for the reasons addressed above.

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 3, 9 and 26-29 recite a specific hybridoma with ATCC Deposit No. PTA-82. However, the specification fails to provide the deposit statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. Such statement would satisfy the enablement requirement of 35 U.S.C. 112. For each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository. See MPEP 2404-2410.02.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

(a) that the deposit has been made under the terms of the Budapest Treaty; **and**

(b) that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent,

would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then the requirements may be satisfied by an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or by a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and establishing that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 C.F.R. 1.807 is provided; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination, or loss of capability to function described in the manner in the specification.

In either case, the identifying information set forth in 37 C.F.R. 1.809(d) should be added to the specification if it is not already present. For deposits made with the ATCC, note that effective 23 March 1988 the depository's address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

See 37 C.F.R. 1.803-1.809 for additional explanation of these requirements.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
6/18/09